# VI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL - 6 2006

**A. SPONSOR IDENTIFICATION**

Musculoskeletal Transplant Foundation
125 May Street
Edison, NJ 08837
Tel: 732-661-0202
http://www.mtf.org

**B. ESTABLISHMENT REGISTRATION NUMBER**

2249062

**C. OFFICIAL CONTACT PERSON**

Nancy Bennewitz
Regulatory Affairs Submission Specialist
Musculoskeletal Transplant Foundation
125 96th Street
Edison, NJ 08837
Tel: 732-661-2381
Nancy_Bennewitz@mtf.org

**D. DATE OF PREPARATION OF THIS SUMMARY**

March 30, 2006

**E. PROPRIETARY (TRADE) NAME**

Allofix™ Anchor

**F. COMMON NAME**

Bone Anchor

**G. CLASSIFICATION NAME**

Smooth or Threaded Metallic Bone Fixation Fastener
Nonabsorbable Polyethylene Surgical Suture

**H. REGULATION NUMBER**

21 CFR 888.3040 and 21 CFR 878.5000

**I. PROPOSED REGULATORY CLASS**

Class II

**J. DEVICE PRODUCT CODE**

MAI, JDW, GAT

## K. PANEL CODE

87 or Orthopedic Devices

## L. DESCRIPTION OF DEVICE

The anchor, suture, and inserter are all packaged together. The kit contains one allograft anchor, loaded with two strands of #2 polyethylene suture, blue, and one strand of white. The anchor and suture are housed in an inserter. The anchor resides at the tip of the tube while the bulk of the suture resides within the inserter handle.

The inserter, with the loaded anchor, et al, delivers the product to the site. The inserter is composed of a plastic body and a stainless steel tube with two #2 sutures. A drill or punch is provided to create a hole to deliver the anchor. The inserter contents are housed within a plastic tray. All components are single use and sterile.

## M. INDICATIONS FOR USE

The Allofix™ Anchor is indicated for use in the attachment of soft tissue to bone in orthopedic procedures.

## N. PREDICATE DEVICE

The Allofix™ Anchor is substantially equivalent to the Smith and Nephew Phoenix 5.0 Allograft Anchor (FDA cleared, K011985).

## O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Both the Allofix™ Anchor and the Phoenix Allograft Anchor have the same indications for use. Allofix™ Anchor and its predicate are both made from machined human allograft bone derived from the tibia or femur recovered from deceased donors. Both Allofix™ Anchor and its predicate require implantation into bone through use of an attached insertion device. The Allograft Anchor™ and its predicate use USP Size Number 2 Braided Polyethylene/Polyester Sutures.

## P. SUMMARY OF STUDIES

Biomechanical testing of the Allofix™ Anchor was performed to investigate whether the anchor meets design requirements. The conclusion of the anchor insertion and fixation test confirmed that the Allofix™ Anchor meets design input requirements for strength. The tests also confirmed that the Allofix™ Anchor dimensions were within design requirements. Insertion repeatability was found to be acceptable and pullout values for fixation strength exceeded those of metal and polymeric devices used for similar types of fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2006

Musculoskeletal Transplant Foundation
% Nancy L. Bennewitz
Regulatory Affairs Submission Specialist
125 May Street, Suite 300
Edison Corp Center
Edison, New Jersey 08837

Re: K061498
Trade/Device Name: Allofix™ Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulation Class: II
Product Code: JDW, MAI
Dated: May 30, 2006
Received: May 31, 2006

Dear Ms. Bennewitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# IV. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Allofix™ Anchor

Indications for Use: The Allofix™ Anchor is indicated for use in soft tissue approximation and/or ligation of orthopaedic procedure.

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061495